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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,935	06/08/2001	Daniel Pinto	13294-002001	1394

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EXAMINER

QIAN, CELINE X

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8m

Office Action Summary

Application No.

09/877,935

Applicant(s)

PINTO ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-12 and 32-35 is/are rejected.
- 7) ☒ Claim(s) 3-8,34 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/5/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-12 and 32-35 are pending in the application.

This Office Action is in response to the amendment filed on 12/29/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/03 has been entered.

Response to Amendment

Claims 1, 2, 9-12 and newly added claim 33 are rejected under 35 U.S.C. 112 1st paragraph for reasons set forth of the record mailed on 9/23/03 and further discussed below.

Claims 9, 32, 34 and 35 are rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

Claims are 3-8, 34 and 35 objected to for reasons discussed below.

Response to Arguments

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9-12 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue the amended claim clarifies that the fragments are within 9kb nucleotide sequence. Further, Applicants argue that the specification discloses a number of different elements within the murine villin gene that affect transcription, and hence have written description support for the claimed nucleotide sequence. Applicants further argue that the specification discloses deletions of 9kb nucleotide sequence which provides written description support for claim 10. Applicants thus conclude that the written description requirement is satisfied by the current amendment.

These arguments have been fully considered but deemed unpersuasive. Although the amended claims limited the fragment to be within a 9kb fragment 5' to the mouse villin gene, the claimed genus still encompasses a large number of nucleic acid molecules that is 5' to the mouse villin gene (it can be any 9kb fragment as long as it is 5' to the villin gene, for example, claim 2 and 33 disclose a 9kb fragment extending 5.5kb upstream from the transcription initiation site and 3.5kb downstream from said site). The specification only discloses one specific 9kb fragment represented by the sequence of SEQ ID NO:1, extending 3.5kb upstream from the transcription start site and 5.5kb downstream from the transcription start site, and four fragments inside this fragment which have tissue specific regulatory activity. As such, the specification fails to describe a representative number of species by their complete structure or other identifying characteristics. With regard to claims 9 and 10, the claims recite a 9kb fragment comprising -3.5kb upstream to the transcription start site to translation start site of the villin gene

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wherein the intron I or part of intron I is deleted. The specification teaches deletion of the entire intron I retains the promoter activity of this fragment. The specification also teaches that deletion of the HS II within this region abolishes promoter function. However, the specification fails to teach whether there are other elements, for example HS I within this region also critical for promoter function. The specification fails to describe any other nucleotide fragments with partial deletion of intron I that retains promoter function. As such, the structural and function relationship between the 9kb nucleotide fragment with partial intron I deletion and its promoter function is missing. Therefore, the written description requirement is not met, and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 32, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 9, 32 and 35, the recitation of “3.5kb upstream from the transcription initiate site to the translation initiation site” renders the claims indefinite because it is unclear what gene the transcription initiate site or the translation site is referring to. In addition, the translation initiation site is downstream from the transcription initiation site. It is unclear how a fragment extending 3.5kb upstream from the transcription start site can cover translation start site. Clarification is required.

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Regarding claims 32 and 35, the recitation of “a nucleotide fragment extend from the HS I to HS VI Dnase-I hypersensitive site to the translation initiation site of the murine villin gene” renders the claims indefinite because it is unclear which region this fragment covers. According to the specification, HS IV is 5’ to HS I, and a fragment extend from HS I to HS IV would not cover the translation initiation site, because the translation initiation site is 3’ to the HS I. As such, the metes and bounds of the claim cannot be established.

Regarding claim 34, the recitation of “which is the sequence identified as SEQ ID NO:1” renders the claim indefinite because it is unclear which sequence the claims are referring to. The parent claim 33 recites a sequence extending 5.5kb upstream and 3.5 downstream from the transcription start site, whereas SEQ ID NO:1 represents the sequence 3.5kb upstream and 5.5kb downstream from the transcription start site. As such, the sequence recited in claim 33 cannot be SEQ ID NO:1.

Double Patenting

Claims 7 and 34 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Objections

Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

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claim(s) in independent form. Claim 35 recites a nucleotide sequence according to claim 32 which comprises nucleotide regions having a regulatory activity affecting the expression of the murine villin gene. The nucleotide sequence of claim 32 inherently comprises such region. Therefore, claim 35 fails to further limit the parent claim.

Claims 3-6 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

